# STATE OF CALIFORNIA DEPARTMENT OF INDUSTRIAL RELATIONS DIVISION OF WORKERS' COMPENSATION

#### NOTICE OF PROPOSED RULEMAKING

# Workers' Compensation - Medical Treatment Utilization Schedule

**NOTICE IS HEREBY GIVEN** that the Administrative Director of the Division of Workers' Compensation (hereinafter "Administrative Director"), exercising the authority vested in her by Labor Code sections 59, 133, 4603.5, and 5307.3, proposes to adopt regulations contained in Article 5.5.2 of Chapter 4.5, Subchapter 1, Division 1, of Title 8, California Code of Regulations, sections 9792.20 through 9792.23.

The regulations concern the adoption of the Medical Treatment Utilization Schedule. The regulations implement, interpret, and make specific sections 77.5, 4604.5 and 5307.27, as adopted by Senate Bill 228 (Chapter 639, Stats. of 2003, effective January 1, 2004), and Labor Code section 4600, and 4604.5, as amended by Senate Bill 899 (Chapter 34, stats. of 2004, effective April 19, 2004).

#### PROPOSED REGULATORY ACTION

The Division of Workers' Compensation, proposes to adopt Article 5.5.2 of Chapter 4.5, Subchapter 1, Division 1, of Title 8, California Code of Regulations, commencing with Section 9792.20:

Section 9792.20	Medical Treatment Utilization Schedule—Definitions
Section 9792.21	Medical Treatment Utilization Schedule
Section 9792.22	Presumption of Correctness, Burden of Proof and Hierarchy of Scientific
	Based Évidence
Section 9792.23	Medical Evidence Evaluation Advisory Committee

# TIME AND PLACE OF PUBLIC HEARING

A public hearing has been scheduled to permit all interested persons the opportunity to present statements or arguments, either orally or in writing, with respect to the subjects noted above. The hearing will be held at the following time and place:

**Date: August 23, 2006** 

Time: 10:00 A.M. to 5:00 P.M., or until conclusion of business

Place: Elihu Harris State Office Building – Auditorium

1515 Clay Street

Oakland, California 94612

The State Office Building and its Auditorium are accessible to persons with mobility impairments. Alternate formats, assistive listening systems, sign language interpreters, or other type of reasonable accommodation to facilitate effective communication for persons with disabilities, are available upon request. Please contact the State Wide Disability Accommodation Coordinator, Stephanie Leach, at 1-866-681-1459 (toll free), or through the California Relay Service by dialing 711 or 1-800-735-2929 (TTY/English) or 1-800-855-3000 (TTY/Spanish) as soon as possible to request assistance.

Please note that public comment will begin promptly at 10:00 a.m. and will conclude when the last speaker has finished his or her presentation or 5:00 p.m., whichever is earlier. If public comment concludes before the noon recess, no afternoon session will be held.

The Administrative Director requests, but does not require, that any persons who make oral comments at the hearing also provide a written copy of their comments. Equal weight will be accorded to oral comments and written materials.

# WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department of Industrial Relations, Division of Workers' Compensation. The written comment period closes at **5:00 P.M.**, on August **23, 2006**. The Division of Workers' Compensation will consider only comments received at the Division by that time. Equal weight will be accorded to comments presented at the hearing and to other written comments received by 5 P.M. on that date by the Division.

Submit written comments concerning the proposed regulations prior to the close of the public comment period to:

Maureen Gray Regulations Coordinator Division of Workers' Compensation, Legal Unit P.O. Box 420603 San Francisco, CA 94142

Written comments may be submitted by facsimile transmission (FAX), addressed to the above-named contact person at (510) 286-0687. Written comments may also be sent electronically (via e-mail) using the following e-mail address: <a href="mailto:dwcrules@dir.ca.gov">dwcrules@dir.ca.gov</a>.

Unless submitted prior to or at the public hearing, Ms. Gray must receive all written comments no later than **5:00 P.M.**, on August 23, 2006.

# **AUTHORITY AND REFERENCE**

The Administrative Director is undertaking this regulatory action pursuant to the authority vested in her by Labor Code sections 133, 4603.5, 5307.3, and 5307.27.

Reference is to Labor Code sections 77.5, 4600, 4604.5, and 5307.27, Labor Code.

#### INFORMATIVE DIGEST / POLICY STATEMENT OVERVIEW

These regulations are required by legislative enactments—Senate Bill 228 (Chapter 639, Stats. of 2003, effective January 1, 2004) and Senate Bill 899 (Chapter 34, stats. of 2004, effective April 19, 2004). Senate Bill 228 included Labor Code section 77.5, which required the Commission on Health and Safety and Workers' Compensation (hereinafter CHSWC) to conduct a survey and evaluation of evidence-based, peer-reviewed, nationally recognized standards of care, and to report its findings and recommendations to the Administrative Director for purposes of the adoption of a medical treatment utilization schedule. Senate Bill 228 also included Labor Code section 5307.27, requiring the Administrative Director, in consultation with CHSWC, to adopt, after public hearings, a medical treatment utilization schedule. Section 5307.27 requires the medical treatment utilization schedule to address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases.

Senate Bill 228 further included Labor Code section 4604.5, which was later amended by Senate Bill 899. Labor Code section 4604.5 provides that upon adoption of the medical treatment utilization schedule pursuant to Labor Code section 5307.27, the recommended guidelines set forth in the schedule are presumptively correct on the issue of extent and scope of medical treatment. Labor Code section 4604.5 also provides that the presumption is rebuttable and may be controverted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines is reasonably required to cure or relieve the injured worker from the effects of his or her injury. The presumption created is one affecting the burden of proof.

Labor Code section 4604.5 further provides that the recommended guidelines set forth in the adopted schedule shall reflect practices that are evidence and scientifically based, nationally recognized, and peer-reviewed. The guidelines shall be designed to assist providers by offering an analytical framework for the evaluation and treatment of injured workers, and shall constitute care in accordance with Labor Code section 4600 for all injured workers diagnosed with industrial conditions.

Labor Code section 4604.5 provides that for injuries occurring on and after January 1, 2004, an injured worker shall be entitled to no more than 24 chiropractic, 24 occupational therapy, and 24 physical therapy visits per industrial injury.

Labor Code section 4600 provides, in pertinent part, that medical, surgical, chiropractic, acupuncture, and hospital treatment, including nursing, medicines, medical and surgical supplies, crutches, and apparatus, including orthotic and prosthetic devices and services, that are reasonably required to cure or relieve the injured worker from the effects of his or her injury shall be provided by the employer. In the case of his or her neglect or refusal reasonably to do so, the employer is liable for the reasonable expense incurred by or on behalf of the employee in providing treatment. Also pertinent to these proposed regulations is subdivision (b) of Labor Code section 4600 which was added by Senate Bill 899. This subdivision provides that, as used in this division and notwithstanding any other provision of law, medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury means treatment that is based upon the guidelines adopted by the administrative director pursuant to Labor Code section 5307.27.

The proposed regulations define the terms used in the controlling statutes, set forth the medical treatment utilization schedule, identify the presumption of correctness and burden of proof required pursuant to the statute and set forth the hierarchy of scientific based evidence to be utilized in specified situations. The proposed regulations further set forth the creation, composition, term of service, and purpose of a medical evidence evaluation advisory committee to advise the Administrative Director on matters concerning the medical treatment utilization schedule.

#### 1. Section 9792.20—Medical Treatment Utilization Schedule—Definitions

This section defines key terms used in these regulations to ensure that the meaning, as used in the regulations, will be clear to the public.

Section 9792.20(a) sets forth the definition for the term "acute." This term is defined as a medical condition lasting less than 3 months.

Section 9792.20(b) sets forth the definition for the term "American College of Occupational and Environmental Medicine (ACOEM)." The term is defined as a medical society of physicians and other health care professionals specializing in the field of occupational and environmental medicine, dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education.

Section 9792.20(c) defines the term "ACOEM Practice Guidelines." This term is defined as the American College of Occupational and Environmental Medicine's Occupational Medicine Practice Guidelines, 2<sup>nd</sup> Edition (2004), published by OEM Press. This section further incorporates the ACOEM Practice Guidelines by reference, and informs the public that a copy may be obtained from OEM Press, 8 West Street, Beverly Farms, Massachusetts 01915 (www.oempress.com).

Section 9792.20(d) sets forth the definition for the term "chronic" as a medical condition lasting 3 months or more.

Section 9792.20(e) sets forth the definition for the term "claims administrator." The term is defined as a self-administered workers' compensation insurer, a self-administered self-insured employer, a self-administered legally uninsured employer, a self-administered joint powers authority, a third-party claims administrator, or the California Insurance Guarantee Association.

Section 9792.20(f) sets forth the definition of the term "evidence-based" as based, at a minimum, on a systematic review of literature published in medical journals included in MEDLINE.

Section 9792.20(g) sets forth the definition of the term "hierarchy of evidence" as establishing the relative weight that shall be given to scientifically based evidence.

Section 9792.20(h) sets forth the definition for the term "medical treatment." The term is defined as care which is reasonably required to cure or relieve the employee from the effects of the industrial injury consistent with the requirements of sections 9792.20-9722.23.

Section 9792.20(i) sets forth the definition for the term "medical treatment guidelines." The term is defined as written recommendations systematically developed through a comprehensive literature search to assist in decision-making about the appropriate health care for specific clinical circumstances.

Section 9792.20(j) sets forth the definition for the term "medical treatment provider." The term is defined as a provider of medical services as well as related services or goods, including but not limited to an individual or facility, a health care service plan, a health care organization, a member of preferred provider organization, or a medical provider network as provided in Labor Code section 4616.

Section 9792.20(k) sets forth the definition for the term "MEDLINE." The term, which is commonly known as PubMed, is defined as the search engine for the National Library of Medicine. The section further sets forth its website address as <a href="https://www.pubmed.gov">www.pubmed.gov</a>.

Section 9792.20(1) sets forth the definition for the term of "nationally recognized" as meaning published in a peer-reviewed medical journal; or developed, endorsed and disseminated by a national organization based in two or more U.S. states; or currently adopted by one or more U.S. state governments or by the U.S. federal government; and is the most current version.

Section 9792.20(m) sets forth the definition of the term "scientifically based." The term is defined as meaning based on scientific literature, wherein the literature is identified through performance of a literature search, the identified literature is graded, and then used as the basis for the guideline.

# 2. Section 9792.21—Medical Treatment Utilization Schedule

This section sets forth the medical treatment utilization schedule.

- (a) This section informs the public that the Administrative Director adopts and incorporates by reference the ACOEM Practice Guidelines, Second Edition (2004), published by OEM Press, into the medical treatment utilization schedule. The section further informs the public that a copy of the ACOEM Practice Guidelines may be obtained from OEM Press, 8 West Street, Beverly Farms, Massachusetts 01915 (www.oempress.com).
- (b) This section explains that the ACOEM Practice Guidelines are intended to assist medical treatment providers by offering an analytical framework for the evaluation and treatment of injured workers. The section further explains that the ACOEM Practice Guidelines are intended to help those who make medical treatment decisions regarding the care of injured workers understand what treatment has been proven effective in providing the best medical outcomes to those workers, in accordance with section 4600 of the Labor Code.
- (c) This section explains that treatment cannot be denied on the sole basis that the condition or injury is not addressed by the ACOEM Practice Guidelines. The section further explains that if this situation is encountered, the claims administrator must authorize treatment, and clarifies that such authorized treatment must be in accordance with other scientifically and evidence-based medical treatment guidelines that are generally recognized by the national medical community, in accordance with subdivisions (b) and (c) of section 9792.22.

# 3. Section 9792.22—Presumption of Correctness, Burden of Proof and Hierarchy of Scientific Based Evidence

This section identifies the presumption of correctness and burden of proof required by the statute and sets forth the hierarchy of scientific based evidence to be utilized in specified situations.

- (a) This section informs the public pursuant to the statute that the ACOEM Practice Guidelines are presumptively correct on the issue of extent and scope of medical treatment and diagnostic services addressed in those guidelines for both acute and chronic medical conditions. The section explains that the presumption is rebuttable and may be controverted by a preponderance of scientific medical evidence establishing that a variance from the schedule is reasonably required to cure or relieve the injured worker from the effects of his or her injury. The section further explains that the presumption created is one affecting the burden of proof.
- (b) This section explains that, pursuant to the statute, for all conditions or injuries not addressed by the ACOEM Practice Guidelines, the treatment and diagnostic service which is authorized must be in accordance with other scientifically and evidence-based medical treatment guidelines that are generally recognized by the national medical community.
- (c)(1) This section sets forth a hierarchy of scientific based evidence to be used to determine the effectiveness of different medical treatments or diagnostic services when the following situations exist:
  - where the medical treatment or diagnostic service provided is not addressed by section 9792.22(a) (medical treatment or diagnostic services that are addressed by the ACOEM Practice Guidelines);
  - where the medical treatment or diagnostic service provided is not addressed by provisions of section 9792.22(b) referring to medical treatment or diagnostic services that are addressed by other medical

- treatment guidelines that are "scientifically and evidence-based" and are "generally recognized by the national medical community[;]"
- where the medical treatment or diagnostic service provided is at variance with the provisions of section 9792.22(a) (medical treatment or diagnostic services that are addressed by the ACOEM Practice Guidelines);
- where the medical treatment or diagnostic service provided is at variance with the provisions of section 9792.22(b) referring to medical treatment or diagnostic services that are addressed by other medical treatment guidelines that are "scientifically and evidence-based" and are "generally recognized by the national medical community[;]"
- where the recommended medical treatment or diagnostic service covered under section 9792.22(b) is at variance with another treatment guideline also covered under section 9792.22(b).

The hierarchy of scientific based evidence is set forth in this section as follows:

- (A) **Level A.** Strong research-based evidence provided by generally consistent findings in multiple (more than one) high quality randomized control studies (RCTs).
- (B) **Level B.** Moderated research-based evidence provided by generally consistent findings in one high-quality RCT and one or more low quality RCTs, or generally consistent findings in multiple low quality RCTs.
- (C) **Level C.** Limited research based evidence provided by one RCT (either high or low quality) or inconsistent or contradictory evidence findings in multiple RCTs.
- (c)(2) This subdivision explains that evidence shall be given the highest weight in the order of the hierarchy of scientific based evidence.

# 4. Section 9792.23—Medical Evidence Evaluation Advisory Committee

This section explains the creation, composition, term of service, and purpose of a medical evidence evaluation advisory committee.

- (a)(1) This subdivision explains that the Medical Director will create a medical evidence evaluation advisory committee to provide recommendations to the Administrative Director on matters concerning the medical treatment utilization schedule. The subdivision further explains that the recommendations of the evidence evaluation advisory committee are advisory only and will not constitute scientifically based evidence.
- (a)(1)(A) This subpart explains that if the Medical Director position becomes vacant, the Administrative Director will appoint a competent person to temporarily assume the authority and duties, as set forth in this section, of the Medical Director until the Medical Director position is filled.
- (a)(2) This subdivision explains that the Medical Director, or his or her designee, will appoint the members of the medical evidence evaluation advisory committee. This subdivision further provides that the medical evidence evaluation advisory committee will consist of 10 members of the medical community representing the following specialty fields:

- (a)(2)(A) This subpart informs the public that one member of the medical evidence evaluation advisory committee will be from the orthopedic field;
- (a)(2)(B) This subpart informs the public that one member of the medical evidence evaluation advisory committee will be from the chiropractic field;
- (a)(2)(C) This subpart informs the public that one member of the medical evidence evaluation advisory committee will be from the occupational medicine field;
- (a)(2)(D) This subpart informs the public that one member of the medical evidence evaluation advisory committee will be from the acupuncture medicine field;
- (a)(2)(E) This subpart informs the public that one member of the medical evidence evaluation advisory committee will be from the physical or occupational therapy field;
- (a)(2)(F) This subpart informs the public that one member of the medical evidence evaluation advisory committee will be from the psychology or psychiatry field;
- (a)(2)(G) This subpart informs the public that one member of the medical evidence evaluation advisory committee will be from the pain specialty field;
- (a)(2)(H) This subpart informs the public that three members of the medical evidence evaluation advisory committee will be appointed at the discretion of the Medical Director or his or her designee.
- (a)(3) This subdivision explains that in addition to the ten members of the medical evidence evaluation advisory committee, the Medical Director, or his or her designee, may appoint an additional three members to the medical evidence evaluation advisory committee. These three additional members will be appointed as subject matter experts for any given topic.
- (b) This section informs the public that the Medical Director, or his or her designee, will serve as the chairperson of the medical evidence evaluation advisory committee.
- (c) This section informs the public that the members of the medical evidence evaluation advisory committee will use the hierarchy of evidence set forth in subdivision (c)(1) of section 9792.22 to evaluate evidence when making recommendations to revise, update or supplement the medical treatment utilization schedule.
- (d) This section explains the terms of service of the members of the medical evidence evaluation advisory committee. The section informs the public that the members of the medical evidence evaluation advisory committee, with the exception of the three subject matter experts, will serve a term of one year period. If at the end of the one year period a successor is not selected, the member of the committee will continue in that position until a successor is selected. The section further informs the public that the subject matter experts will serve in the medical evidence evaluation advisory committee until the evaluation of the subject matter guideline is completed.
- (f) This section informs the public that the Administrative Director, in consultation with the medical evidence evaluation advisory committee, may revise, update, and supplement the medical treatment utilization schedule as necessary.

# DISCLOSURES REGARDING THE PROPOSED REGULATORY ACTION

The Administrative Director has made the following initial determinations:

- Significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states: None.
- Adoption of this regulation will not: (1) create or eliminate jobs within the State of California; (2) create new businesses or eliminate existing businesses within the State of California; or (3) affect the expansion of businesses currently doing business in California.
- Effect on Housing Costs: None.
- Cost impacts on representative private person or business: The Administrative Director has determined that the proposed regulations will not have a significant adverse economic impact on representative private persons or directly affected businesses.
- There will be some small costs related to the purchase of the ACOEM Practice Guidelines at the cost of \$195.00 per book. There may also be some costs related to the purchase of other medical treatment guidelines that are evidence and scientifically based, nationally recognized and peer-reviewed. However, it is expected that many business already own these guidelines as part of their ongoing business expenses.

# FISCAL IMPACTS

- Costs or savings to state agencies or costs/savings in federal funding to the State: None.
- Local Mandate: None. The proposed regulations will not impose any new mandated programs or increased service levels on any local agency or school district. The potential costs imposed on all public agency employers by these proposed regulations, although not a benefit level increase, are not a new State mandate because the regulations apply to all employers, both public and private, and not uniquely to local governments. The Administrative Director has determined that the proposed regulations will not impose any new mandated programs on any local agency or school district. The California Supreme Court has determined that an increase in workers' compensation benefit levels does not constitute a new State mandate for the purpose of local mandate claims because the increase does not impose unique requirements on local governments. See County of Los Angeles v. State of California (1987) 43 Cal.3d 46. The potential costs imposed on all public agency employers and payors by these proposed regulations, although not a benefit level increase, are similarly not a new State mandate because the regulations apply to all employers and payors, both public and private, and not uniquely to local governments.
- Cost to any local agency or school district that is required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4 of the Government Code: None. (See "Local Mandate" section above.)
- Other nondiscretionary costs/savings imposed upon local agencies: None. The proposed regulations do not apply to any local agency or school district. (See

#### EFFECT ON SMALL BUSINESS

The Administrative Director has determined that the proposed regulations will result in small initial costs to small businesses if they have not already purchased the ACOEM Practice Guidelines at the cost of \$195.00 per book. There may also be some costs related to the purchase of other medical treatment guidelines that are evidence and scientifically based, nationally recognized and peer-reviewed if these business do not already own these guidelines as part of their ongoing business practices.

#### CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Administrative Director must determine that no reasonable alternative considered or that has otherwise been identified and brought to the Administrative Director's attention would be more effective in carrying out the purpose for which the actions are proposed, or would be as effective and less burdensome to affected private persons than the proposed actions.

The Administrative Director invites interested persons to present reasonable alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

# PUBLIC DISCUSSIONS OF PROPOSED REGULATIONS

The text of the draft proposed regulations was made available for pre-regulatory public comment from June 23, 2005 through July 8, 2005 through the Division's Internet website (the "DWC Forum"), as required by Government Code section 11346.45.

# AVAILABILITY OF INITIAL STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, RULEMAKING FILE AND DOCUMENTS SUPPORTING THE RULEMAKING FILE/INTERNET ACCESS

An Initial Statement of Reasons and the text of the proposed regulations in plain English have been prepared and are available from the contact person named in this notice. The entire rulemaking file will be made available for inspection and copying at the address indicated below.

As of the date of this Notice, the rulemaking file consists of the Notice, the Initial Statement of Reasons, proposed text of the regulations, pre-rulemaking comments and the Economic Impact Statement (Form STD 399). Also included are studies and documents relied upon in drafting the proposed regulations.

In addition, the Notice, Initial Statement of Reasons, and proposed text of the regulations being proposed may be accessed and downloaded from the Division's website at <a href="www.dir.ca.gov">www.dir.ca.gov</a>. To access them, click on the "Proposed Regulations – Rulemaking" link and scroll down the list of rulemaking proceedings to find the Medical Treatment Utilization Schedule link.

Any interested person may inspect a copy or direct questions about the proposed regulations and any supplemental information contained in the rulemaking file. The rulemaking file will be available for inspection at the Department of Industrial Relations, Division of Workers' Compensation, 1515 Clay Street, 17<sup>th</sup> Floor, Oakland, California 94612, between 9:00 A.M. and 4:30 P.M., Monday through Friday. Copies of the proposed regulations, Initial Statement of Reasons and any information contained in the rulemaking file may be requested in writing to the contact person.

# CONTACT PERSON FOR GENERAL QUESTIONS

Non-substantive inquiries concerning this action, such as requests to be added to the mailing list for rulemaking notices, requests for copies of the text of the proposed regulations, the Initial Statement of Reasons, and any supplemental information contained in the rulemaking file may be requested in writing at the same address. The contact person is:

Maureen Gray Regulations Coordinator Department of Industrial Relations Division of Workers' Compensation P.O. Box 420603 San Francisco, CA 94142 E-mail: mgray@dir.ca.gov

The telephone number of the contact person is (510) 286-7100.

# CONTACT PERSON FOR SUBSTANTIVE QUESTIONS

In the event the contact person above is unavailable, or for questions regarding the substance of the proposed regulations, inquiries should be directed to:

Minerva Krohn Division of Workers' Compensation P.O. Box 420603 San Francisco, CA 94142 E-mail: mkrohn@dir.ca.gov

The telephone number of this contact person is (510) 286-7100.

# AVAILABILITY OF CHANGES FOLLOWING PUBLIC HEARING

If the Administrative Director makes changes to the proposed regulations as a result of the public hearing and public comment received, the modified text with changes clearly shown will be made available for public comment for at least 15 days prior to the date on which the regulations are adopted.

#### AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Upon its completion, the final Statement of Reasons will be available and copies may be requested from the contact person named in this notice or may be accessed on the Division's website at www.dir.ca.gov.

# **AUTOMATIC MAILING**

A copy of this Notice, the Initial Statement of Reasons, and the text of the regulations, will automatically be sent to those interested persons on the Administrative Director's mailing list.

If adopted, the regulations with any final amendments will appear in title 8 of the California Code of Regulations, commencing with section 9792.20. The text of the final regulations also may be available through the website of the Office of Administrative Law at www.oal.ca.gov.